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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,198	06/19/2002	Christopher Gregory Proud	9013-42	1487

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,198	PROUD ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/14/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-22* is/are pending in the application.

4a) Of the above claim(s) *15 and 19-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 June 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/19/02 & 12/20/01*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 11-22 are pending.

Election/Restrictions

Applicants' election (filed 11/14/05) of Group I, claims 11-14 and 16-18 with traverse is acknowledged. The traversal is on the ground(s) that as Haghighat et al. do not teach or suggest that buffer A is a pharmaceutically acceptable carrier (see page 3 the last paragraph of the applicants' response); and thus, the Haghlighat's reference is not qualified for the obvious (prior) art against the claimed pharmaceutical composition comprising a polypeptide that comprises the instant SEQ ID NO:1 (see page 3, the Office action mailed 10/14/05) and the carrier. Therefore, Applicants infer that the claims meet the requirement for unity of invention.

The applicants' argument is found to be unpersuasive because the buffer A comprising Tris-HCl (pH 7.5) is considered to be a pharmaceutically acceptable carrier. Since the Office does not have a laboratory to test the reference buffer, it is applicant's burden to show that the buffer A is not the carrier thereof. Moreover, on columns 48, line 66 to column 49, line 29, Hentze et al. teach the pharmaceutical composition comprising the therapeutic, e.g., eIF4G protein which comprises the sequence "KKRYDREFLLGF which reads on the instant SEQ ID NO:1, and a pharmaceutically acceptable carrier.

Thus, the requirement is still deemed proper and is therefore made FINAL. Note that Examiner has pointed out an typo-error in the restriction requirement mailed 10/14/05 (see the attached interview summary) wherein Group I should include claims 11-14 (instead of 11-15)

and 16-18 because claim 15 belongs to Group III which has been clearly set forth in said requirement.

Claims 15 and 19-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. The pending claims 11-14 and 16-18 are under examination to the extent that they are drawn to the elected invention.

Objection to Claims/Specification

The disclosure is objected to because of the following informalities:

(1) Claim 11-12 and 16-18 are objected to because the claim recite amino acid sequences without the corresponding sequence identifiers (SEQ ID NOs:_).

(2) The drawings, Figures 4-6 and 12 are objected to because the drawings set forth the amino acid sequences without the corresponding sequence identifiers (SEQ ID NOs:_).

Appropriate correction is required.

Objection to Drawings

The drawings, Figures 9 and 10 are object to because the Figures contain cross-lines over inserts that indicate conditions/steps for the "serum starve" set forth in Figures 9-10. The inserts should be separated from the lines. Also, the labeling " 1 h @ 50 μM" in Figure 9, should be clarified because "@" is unclear.

IDS

The references listed in the IDS filed 6/19/02 and the IDS filed 12/20/01 have been considered by Examiner.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 11-14 and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 16-18 are vague and indefinite because it is not apparent whether or not "variable amino acid" refers to any amino acid or the amino acid variable or derivative, e.g., chemically synthesized amino acid analogue. Dependent claims 13-14 are also rejected.

Claim 12 recites the amino acid sequences "RVRYSDQLLDL" and "RIIYDRKL"; both sequences do not read on the sequence (the instant SEQ ID NO:5) set forth in claim 1. Thus, claim 12 recitation lacks antecedent basis in claim 1 from which claim 2 depends.

Claims 13, 16 and 18 are vague and indefinite because the claims lack antecedent basis because the peptide consisting of 7-9 amino acid residues does not read on the length (10 amino acids) of SEQ ID NO:5 of instant claim 11 from which claim 13 depends from, and claims 16 and 18 . The SEQ ID NO:5 appears to be the common motif (see page 3, lines 7-8, the specification) critical for biological function.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12, 14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hentze et al. (US Pat. NO. 6610508) as is evidenced by the fact, set forth in the page 4 of the instant specification, that the peptide of eIF4G residues 569-580 is capable of inducing programmed cell death.

Hentze et al. teach a process of administering to a subject the pharmaceutical composition comprising the therapeutic, e.g., eIF4G-like protein (see columns 48, line 66 to column 49, line 31) which comprises the sequence, i.e., residues 569-580 "KKRYDREFLLGF" which reads on the instant SEQ ID NO:1 (claim 12) and the peptide sequence set forth in claim 11; wherein the eIF4G-like protein is human eIF4G (column 14, line 58), and said sequence consisting of residues 569-580 is the eIF4E-binding domain (column 15, lines 11-12 and the patent SEQ ID NO:2). The Hentze et al. teaching is applied to instant claims 11-12.

On column 11, lines 16-18, Hentze et al. teach the process is for treating a disorder state comprising administering to a subject the polypeptide comprising eIF4G protein; the said

disorder state is cancer, e.g., carcinomas (see column 31, lines 5-34), as applied to instant claims 14 and 17.

Yet, Hentze et al. do not provide working example to expressly indicate/teach that the process is directed to inducing programmed cell death in the subject to which the above-mentioned composition is administered.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer the polypeptide comprising the eIF4E-binding domain to induce programmed cell death. One skilled in the art would have been motivated to do this because the following reasons.

Hentze et al. have taught the method of administering to a subject (including cancer patient) the pharmaceutical composition comprising the *therapeutic*, e.g., the polypeptide comprising the eIF4E-binding domain, i.e., residues 569-580 of eIF4G (see the above statement and column 48, line 67 to column 49, line 3). Also, Hentze et al. have taught that said method is useful for treating disorder state (e.g., tumor) (see column 30-31). When administered, it would reasonably lead to inducing the programmed cell death in the subject since the peptide since eIF4G residues 569-580 is capable of inducing programmed cell death (see the specification (page 4, the 1st paragraph).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The

examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel W. Liu, Ph.D.
December 5, 2005

JON WEBER
SUPERVISORY PATENT EXAMINER